

Remarks

The Examiner's Answer mailed April 30, 2008 has been received and reviewed. Claims 1, 9, 10, 18, 20, 30, 32, 42, 45, 47, 49, 51, 56, 63, 75, and 78 are amended. Claims 76 and 77 are canceled, without prejudice. Claims 79-88 are added. Thus, after entry of the amendments, claims 1-18, 20-75, and 78-88 will be pending and under consideration. Reconsideration and withdrawal of the rejections are respectfully requested.

Claim Amendments

Claims 1, 10, 20, and 32 are amended to recite providing a miscible polymer blend that is capable of controlling delivery of the active agent, comprising: providing a first miscible polymer having a solubility parameter, providing a second polymer selected to be miscible with the first polymer and having a solubility parameter, and combining the first miscible polymer and the second polymer to form the miscible polymer blend. Support for the amendment may be found in Applicants' disclosure at, for example, page 5, lines 7-19.

Claims 56 and 63 are amended to recite combining the first miscible polymer with the second polymer to form an active agent delivery system comprising a miscible polymer blend and having the preselected dissolution time through a preselected critical dimension of the miscible polymer blend. Support for the amendment may be found in Applicants' disclosure at, for example, page 4, line 27 through page 5, line 19.

Claims 1, 10, 20, 32, 56, 63, 75, and 78 are amended to recite that the difference between at least one solubility parameter of each of the polymers is no greater than about $3 \text{ J}^{1/2}/\text{cm}^{3/2}$. Support for the amendments may be found in Applicants' disclosure at, for example, page 18, line 28 through page 19, line 4.

Claims 9, 18, 30, and 42 are amended to recite that the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the

polymers is no greater than about $3 \text{ J}^{1/2}/\text{cm}^{3/2}$. Support for the amendments may be found in Applicants' disclosure at, for example, page 18, line 28 through page 19, line 4.

Claims 9, 18, 30, and 42 are also amended to change the claim from which each amended claim depends.

Claims 32, 45, 47, 49, 51, 63, and 78 are amended to correct obvious typographical errors. With respect to the amendments to claims 32, 63, and 78, recitation of "polyphenylene oxide" is found in the text added to the specification in the Amendment and Response filed November 1, 2006, in the third paragraph to begin on page 6 of the Amendment and Response.

Claims 75 and 78 are amended to correct antecedent basis.

New claims 79 and 80 are drawn to methods of forming a tunable active agent delivery system. Support for new claims 79 and 80 may be found in Applicants' disclosure at, for example, page 12, lines 14-17; page 16, line 3 through page 19, line 21; page 29, line 30 through page 32, line 23; and page 58, line 22 through page 61, line 24.

New claims 81-88 are drawn to embodiments specifying particular ways of incorporating the active agent into the active agent delivery system. Support for new claims 81, 83, 85, and 87 may be found in Applicants' disclosure at, for example, page 12, lines 18-28. Support for new claims 82, 84, 86, and 88 may be found in Applicants' disclosure at, for example, from page 12, line 29 through page 13, line 12.

The 35 U.S.C. §102 Rejections

The Examiner rejected claims 1-18 and 20-78 under 35 U.S.C. §102(e) as being anticipated by Sirhan *et al.* (U.S. 2002/0082679 A1). The Examiner also rejected claims 1-18 and 20-78 under 35 U.S.C. §102(b) as being anticipated by Hossainy *et al.* (U.S. 6,153,252). The Examiner further rejected claims 1-18 and 20-78 under 35 U.S.C. §102(b) as being anticipated by

Whitbourne *et al.* (U.S. 6,110,483). Claims 76 and 77 are canceled. Applicants respectfully traverse the rejections as they apply to claims 1-18, 20-75, and 78.

Claims 1, 10, 20, 32, 56, 63, 75, and 78 are independent. The remaining claims depend, directly or indirectly, from one of the independent claims. Thus, remarks that refer to one or more independent claims apply equally to any claim that depends from a referenced independent claim. In the event that the present rejections may be applied to one or more of new claims 79-88, Applicants respectfully further traverse the application of the present rejections to new claims 79-88.

M.P.E.P. §2131 states, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Each independent claim is directed to methods that include forming a miscible polymer blend particularly suited for use in an active agent delivery system. Each independent claim recites in some form—e.g., "selecting a second polymer" or "a second polymer selected" to be miscible with another polymer—the concept of selecting a second polymer for inclusion in the miscible polymer blend based on certain specified criteria. In particular, the second polymer is selected to be miscible with the first polymer. For brevity in the remarks that follow, reference to any one of: a second polymer "selected" to be, or "selecting" a second polymer to be (or any other equivalent phrase), miscible with another component of the miscible polymer blend includes the other. The second miscible polymer is selected from the groups recited in Applicants' claims (e.g., claim 1 and claim 10). Further, the second miscible polymer is selected so that the difference between at least one solubility parameter of each of at least two polymers is no greater than about $3 \text{ J}^{1/2}/\text{cm}^{3/2}$. For brevity, reference in the following remarks to the second polymer being selected based on "criteria recited in Applicants' claims" or an equivalent phrase refers to (a) miscibility with the first polymer, (b) selected from the recited types of polymers, and (c) so that the difference between at least one solubility parameter of the first polymer and at least one

solubility parameter of the second polymer is no greater than about $3 \text{ J}^{1/2}/\text{cm}^{3/2}$. Also, reference to "the recited difference in solubility parameters" refers to the difference between at least one solubility parameter of the first polymer and at least one solubility parameter of the second polymer being no greater than about $3 \text{ J}^{1/2}/\text{cm}^{3/2}$.

Hossainy *et al.* teach processes for coating stents. Although Hossainy *et al.* teach certain types and classes of polymers from which polymers of Applicants' miscible polymer blend may be selected, Hossainy *et al.* lists over 30 classes of polymers that encompass innumerable species of polymers (arguably thousands if not hundreds of thousands or more) at columns 4 and 5. This list includes references to a handbook (The Handbook of Biodegradable Polymers), an encyclopedia (The Encyclopedia of Polymer Science), journal articles (in Polymer Preprints and Journal of Biomaterials Research), and patents (16 patents).

Whitbourne *et al.* teach polymer coatings for medical devices. Whitbourne *et al.* teach more than a dozen classes of polymers in columns 5 and 6, which, as in Hossainy *et al.*, include innumerable species of polymers. Whitbourne *et al.* also includes polymers discussed in two encyclopedias (Concise Encyclopedia of Polymer Science and Engineering, and Kirk-Othmer Concise Encyclopedia of Chemical Technology).

Sirhan *et al.* teach luminal prosthetic devices that allow for controlled release of a therapeutic agent (Sirhan *et al.*, Abstract). More than a dozen classes of suitable polymers are listed in paragraphs [0119] and [0120], including "mixtures, copolymers, and combinations thereof" for each set of polymers.

While the specific disclosures of Hossainy *et al.*, Whitbourne *et al.*, and Sirhan *et al.* (collectively, "the cited documents") differ somewhat, the relevant disclosure for analysis of the rejections is the same: each reference identifies a vast number of individual polymer species. Moreover, the issues on which each rejection is based are the same: the Examiner asserts that each reference teaches the polymer combination recited in Applicants' claims. Consequently, unless otherwise specifically indicated, the remarks that follow apply to each rejection.

Not only do the cited documents include an extremely long list of polymers (e.g., over 30 classes in Hossainy *et al.*, over a dozen classes in each of Whitbourne *et al.* and Sirhan *et al.*), but there are numerous examples listed for several of the classes of polymers. Furthermore, each of the polymers specifically cited at page 3 of the Examiner's Answer represents many individual polymers. More than a dozen cellulose acetate butyrate (CAB) polymers are commercially available (e.g., Eastman). If variations between individual polymers based on such characteristics as, for example, acetate:butyrate ratio, molecular weight, and/or percent esterification are considered, an infinite number of CAB polymers are possible. Also, hundreds of individual polyethylene vinyl acetate (PEVA) polymers are commercially available (e.g., DuPont), with an infinite number of additional PEVA polymers possible by modifying, for example, the ethylene:vinyl acetate ratio and/or molecular weight. Similarly, with respect to polymers specifically identified at page 5 of the Examiner's Answer, hundreds of polyurethanes are commercially available from a number of suppliers (e.g., Bayer, Dow, etc.) and an infinite number of additional polyurethanes are possible. Also, an infinite number of possible polyamides and polyesters are possible. A similar situation exists for polymers specifically identified on page 7 of the Examiner's Answer. An infinite number of, for example, polyurethanes, polyethers, and epoxy polymers are possible. Thus, each polymer type listed in each of the cited documents is not simply one material, but instead represents a collection of many individual polymer species.

The Examiner repeatedly asserts that the cited documents teach the same polymer combinations as recited in Applicants' claims. Applicants respectfully disagree. The cited documents describe many of the same classes and/or types of polymers from which the polymers used to form the miscible polymer blends recited in Applicants' claims may be selected. The cited documents, however, fail to set forth the various specific polymer combinations recited in the claims. The Examiner seems to base these rejections on the assumption that all polymers of one class or type (e.g., hydrophobic cellulose derivative, polyurethane, polyvinyl homopolymer

or copolymer, etc.) have the same solubility parameter so that selecting any polymers within the recited types or classes of polymers will necessarily result in a polymer combination having the recited difference in solubility parameter. No support has been given for this assumption. Moreover, Applicants respectfully submit that this is not necessarily true, particularly when there are so many different individual polymer species represented by one polymer class or type (as discussed above). This is analogous to suggesting that all polymers of one type (e.g., hydrophobic cellulose derivative, polyurethane, polyvinyl homopolymer or copolymer, etc.) have, for example, the same molecular weight, degree of crosslinking, glass transition temperature, etc.

There is simply no teaching or suggestion in the cited documents to convey to one skilled in the art which polymers to select so that the second polymer will be miscible with the first polymer and possess the recited difference in solubility parameters with respect to the first polymer. In fact, for example, many polymers from among those encompassed by the recited types of second polymers can fail to provide at least one solubility parameter that differs from at least one solubility parameter of one or more first polymers by no greater than $3 \text{ J}^{1/2}/\text{cm}^{3/2}$. For example, one can imagine a chemical stockroom with a set of shelves against one wall. On the shelves are containers of all possible first polymers recited in one of Applicants' independent claims (e.g., claim 1, claim 10, etc.). Against another wall is another set of shelves with containers of all possible polymer species from among the types of possible second polymers recited in the same claim. The cited documents provide no more guidance toward the subject matter of Applicants' claim than mere entry into the stockroom: myriad possible polymer combinations exist and there is no guidance as to which polymers to select in order to obtain the miscible polymer blends recited in the claim. Randomly taking a container off of a shelf holding the recited possible first polymers and another container off of a shelf holding the possible recited second polymers will not necessarily result in a combination of polymers that are miscible with one another and have the recited difference in solubility parameters.

The Examiner suggests that the claims of Sirhan *et al.*, Whitbourne *et al.*, and Hossainy *et al.* provide guidance as to particular polymers for inclusion in the polymer combinations, stating with respect to the claims of Sirhan *et al.*, "[T]he polymers claimed by [Applicants] are also claimed within Sirhan, thus the polymers are hardly laundry lists of ingredients rather they are essential ingredients to the claimed invention." (Office Action, page 15). However, even this asserted guidance fails to direct one skilled in the art to the particular polymer combinations encompassed by the miscible polymer blends recited in Applicants' claims. Applicants do not dispute that the very general disclosures of polymer classes in each of Sirhan *et al.*, Whitbourne *et al.*, and Hossainy *et al.* encompass certain polymers included in the miscible polymer blends recited in Applicants' claims. The issue is the relative scope of the disclosures of the cited documents versus the scope of polymer combinations represented by the recited miscible polymer blends. Applicants' claims recite miscible polymer blends that are a relatively small and specific subset of the innumerable possible polymer combinations disclosed in each of Sirhan *et al.*, Hossainy *et al.*, and Whitbourne *et al.* Moreover, none of the cited documents directs one skilled in the art to the relatively small and specific subset of polymer combinations represented by the miscible polymer blends recited in Applicants' claims. Even when considering the claims of the cited documents, the lack of direction toward the miscible polymer blends in Applicants' claims illustrated immediately above remains. Randomly taking polymers from the subgenera listed in the claims of Sirhan *et al.*, Whitbourne *et al.*, and/or Hossainy *et al.* will not necessarily result in a combination of polymers that are miscible with one another and have a difference in solubility parameter of no greater than $3 \text{ J}^{1/2}/\text{cm}^{3/2}$.

Thus, while the cited documents describe general polymer combinations, contrary to the Examiner's repeated assertion, the cited documents do not direct one to the particular subset of polymer combinations recited in Applicants' claims merely by disclosing some of the same general types of polymers and polymer classes from which the polymers in the recited miscible polymer blends may be selected.

The cited documents fail to set forth all of the features of the miscible polymer blends recited in Applicants' claims. Therefore, for at least these reasons, Applicants submit that claims 1-18, 20-75, and 78-88 are novel over each of Sirhan *et al.*, Hossainy *et al.*, and Whitbourne *et al.* Applicants therefore respectfully request that the rejections be withdrawn.

In addition, the Examiner ignores any "selecting" step as allegedly being a mental process or abstract idea, and therefore asserts that this feature—e.g., "selecting a second polymer" or "a second polymer selected" to be miscible with the first polymer—can be ignored for patentability purposes. The Examiner's Answer states, "[Applicants'] attempt of limiting the independent claims so the second polymer is **selected** to be miscible with the first polymer or so that it has some type of relationship with the active ingredient is a **mental process or abstract idea** and is not a patentable difference in view of the prior art." (Examiner's Answer, page 14, *emphases in original*). Applicants respectfully disagree.

M.P.E.P. §2106(IV)(C)(2) states that claims such as Applicants' claims are eligible for patent protection if they are a practical application of a 35 U.S.C. §101 judicial exception such as, for example, a mental process or an abstract idea. A claimed invention is directed to a practical application of a 35 U.S.C. §101 judicial exception when it:

- (A) "transforms" an article or physical object to a different state or thing; or
- (B) otherwise produces a useful, concrete, and tangible result.

Applicants respectfully submit that the subject matter recited in Applicants' claims provides a material transformation and produces a useful, concrete, and tangible result. Accordingly, under either analysis, selecting the second polymer according to the criteria recited in the claims is, indeed, a patentable difference in view of the prior art and the rejections of Applicants' claims based on ignoring this feature of Applicants' claims is improper.

In the present application, Applicants' claimed methods transform the individual polymers and the active agent into an active agent delivery system. Selecting the second polymer in relation to the first polymer and based on the recited criteria contributes to the controlled

delivery of the active agent. It provides particular properties to the resultant combination of components in the composition. Moreover, whether expressly recited as a method step or inherent in the structure of the claims, the selected polymers are combined to form a miscible polymer blend. For at least this reason, each of Applicants' independent claims, when considered as a whole, results in the physical transformation of matter influenced at least in part by selecting the second polymer in relation to the first polymer and the criteria recited in Applicants' claims. Selecting the second polymer in this way is therefore a patentable distinction over the prior art and must be considered in relation to the cited documents.

In addition, Applicants' methods provide a useful, concrete, and tangible result. A process provides a tangible result if it produces a real world result. M.P.E.P. §2106 (IV)(C)(2)(b). The formation of a miscible polymer blend and an active agent delivery system is, self-evidently, a real world result. A process provides a concrete result if the process produces a result that can be substantially repeatable. M.P.E.P. §2106(IV)(C)(2)(c). The repeatability of producing a miscible polymer blend by selecting the second polymer as recited in Applicants' claims has not been questioned. For an invention to be "useful" it must provide a utility that is (i) specific, (ii) substantial and (iii) credible. M.P.E.P. §2106(IV)(C)(2)(a). The utility of producing a miscible polymer blend by selecting the second polymer as recited in Applicants' claims is acknowledged by the Office Action (Office Action, page 14). Consequently, Applicants' claims provide a useful, concrete, and tangible result.

Therefore, whether because practicing Applicants' claims results in a transformation of matter or provides a useful, concrete, and tangible result, selecting the second polymer in relation to the first polymer and according to the criteria recited in the claims is, indeed, a patentable difference in view of the prior art. For at least this reason, selecting the second polymer as recited in Applicants' claims must be considered in relation to the cited documents.

The patentability of the selection feature of Applicants' claims is further established by the logic employed by the Federal Circuit in *In re Gulak*, 217 USPQ 401 (Fed.Cir. 1983). In *In re Gulak*, the Federal Circuit reversed a decision of the Board of Patent Appeals and Interferences in which the Board upheld the Examiner's rejection of a claim based on the Examiner's refusal to consider a feature of the appealed claim as alleged unpatentable printed matter. While *In re Gulak* addresses printed material, the decision is instructive in the present case because the Federal Circuit reveals the logic behind the inquiry of when allegedly unpatentable subject matter should be considered when examining claims.

The invention in *In re Gulak* was a band or ring on which numerical digits were imprinted according to an algorithm. The claim was rejected over a prior art band having imprinted digits for purposes of support and display. The printed matter displayed on the prior art band was not arranged in any particular order. *Id.* at 405. In contrast, the appealed claims exploited the endless nature of the band by positioning each digit in a unique location with respect to every other digit on the band according to a described algorithm. The appellant and the Board agreed that the sole difference between the appealed claim and the prior art resided in the content of the printed matter. The Board, however, declined to accord the printed matter any patentable weight. *Id.* at 404.

The Federal Circuit analyzed whether any new and unobvious functional relationship existed between the printed material and the band. *Id.* at 404. The Federal Circuit found a functional relationship that established differences between the appealed claim and the prior art sufficient to establish patentability. *Id.*

The differences between the appealed claims and [the prior art] reside in appellant's particular sequence of digits Q, and in the derivation of that sequence of digits. These features are critical to the invention disclosed by the appealed claims. [The prior art] neither discloses nor suggests either feature. *Id.* at 405.

In the present case, one difference between Applicants' claims and the cited documents resides in selecting the second polymer according to particular criteria. These criteria are responsible for

imparting to the miscible polymer blend desirable active agent delivery qualities. The cited documents neither teach nor suggest the criteria recited in Applicants' claims or selecting a second polymer based on those criteria. Thus, selecting the second polymer according to the criteria recited in Applicants' claims bears a functional relationship to the resulting miscible polymer blend that establishes differences between the recited miscible polymer blends and the polymer compositions described in the cited documents. Consequently, the reasoning of *In re Gulak* mandates that selecting the second polymer, contrary to the position of the Examiner, is indeed a patentable distinction that must be considered when examining claims.

Applicants' claims recite the cognitive and discretionary step of selecting the second polymer to be miscible with the first polymer and to possess a solubility parameter that differs from the solubility parameter of the first polymer by no greater than $3 \text{ J}^{1/2}/\text{cm}^{3/2}$. This cognitive and discretionary portion of the polymer selection process is a patentable distinction, as discussed immediately above, and is neither taught nor suggested in the cited documents. Accordingly, if this feature is considered during examination of Applicants' claims, the cited documents cannot anticipate Applicants' claims.

Each of the cited documents fails to teach, expressly or inherently, a method that includes forming a miscible polymer blend by the conscious, deliberate, and discretionary step of selecting a second polymer from among the recited group of suitable second polymers based on miscibility with, and the recited difference in solubility parameter compared to, a polymer from among the recited groups of suitable first polymers. Therefore, the cited documents cannot anticipate Applicants' claims. Therefore, for at least these reasons, Applicants submit that claims 1-18, 20-75, and 78-88 are novel over each of Sirhan *et al.*, Hossainy *et al.*, and Whitbourne *et al.* Applicants therefore respectfully request that the rejections be withdrawn.

Finally, the cited documents cannot anticipate Applicants' claims because there is no 35 U.S.C. § 112, first paragraph, support for Applicants' claims in the cited documents. Put another way, if either Sirhan *et al.*, Hossainy *et al.*, or Whitbourne *et al.* had attempted to add one

or more claims comparable to Applicants' claims during prosecution, the claims would have been rejected as introducing new matter into the application and/or under 35 U.S.C. § 112, first paragraph, as lacking written description in the specification and/or lacking enablement.

The subgenus of polymer combinations reflected in Applicants' claims—those prepared by selecting the second polymer based on miscibility with, and difference in solubility parameter between, a recited first polymer—is not described in any of the cited documents and, therefore, any claim that recited such a feature, if added to any of the cited documents, would have been rejected as introducing new matter into the application. None of the cited documents describes selecting polymers based on their miscibility and/or differences in solubility parameter, generally, or in relation to polymers from any of the recited types of first polymers in particular.

M.P.E.P. §2121.01 provides Examiners with specific instructions as to the enablement required in the disclosure of a document on which an anticipation rejection is based:

"In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, *the stated test is whether a reference contains an 'enabling disclosure'...*" *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). The disclosure in an assertedly anticipating reference *must provide an enabling disclosure of the desired subject matter*; mere naming or description of the subject matter is insufficient, *if it cannot be produced without undue experimentation*. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003). (M.P.E.P. §2121.01, emphases added.)

Applicants respectfully submit that the disclosure of genera of polymers by the cited documents fails to enable one of ordinary skill in the art to practice the desired subject matter—i.e., Applicants' claimed methods.

With regard to the written description requirement of 35 U.S.C. §112, first paragraph, M.P.E.P. §2163.05 states:

The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry

list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species).

An amendment introducing one or more claims comparable to Applicants' claims into any one of the cited documents would require introducing narrowing limitations or elements unsupported by the disclosure of the cited document. Consequently, such a claim, if added to any of the cited documents, would have been rejected as lacking written description support.

Because Applicants' Representative's review of the cited documents did not locate adequate support for Applicants' present claims, Applicants respectfully request the Examiner to review each of the cited documents in this manner (with respect to new matter, enablement, and written description). If the Examiner does not agree with Applicants' position, Applicants request clarification of how each of the cited documents would provide support for Applicants' claims sufficient for the present anticipations rejections to stand.

For at least this reason, Applicants submit that claims 1-18, 20-75, and 78-88 are novel over Sirhan *et al.*, Hossainy *et al.*, and Whitbourne *et al.* Applicants therefore respectfully request that the rejections be withdrawn.

In summary, Applicants submit that claims 1-18, 20-75, and 78-88 are novel over Sirhan *et al.* and request that the rejection of claims 1-18, 20-75, and 78 under 35 U.S.C. §102(b) as being anticipated by Sirhan *et al.* be withdrawn. Further, Applicants submit that claims 1-18, 20-75, and 78-88 are novel over Hossainy *et al.* and request that the rejection of claims 1-18, 20-75, and 78 under 35 U.S.C. §102(b) as being anticipated by Hossainy *et al.* be withdrawn. Applicants further submit that claims 1-18, 20-75, and 78-88 are novel over Whitbourne *et al.* and request that the rejection of claims 1-18, 20-75, and 78 under 35 U.S.C. §102(b) as being anticipated by Whitbourne *et al.* be withdrawn.

The 35 U.S.C. §103 Rejections

The Examiner rejected claims 1-18 and 20-78 under 35 U.S.C. §103(a) as being unpatentable over Sirhan *et al.* (U.S. 2002/0082679 A1). The Examiner also rejected claims 1-18 and 20-78 under 35 U.S.C. §103(a) as being unpatentable over Hossainy *et al.* (U.S. 6,153,252). The Examiner further rejected claims 1-18 and 20-78 under 35 U.S.C. §103(a) as being unpatentable over Whitbourne *et al.* (U.S. 6,110,483). Claims 76 and 77 are canceled. Applicants respectfully traverse the rejections as they apply to claims 1-18, 20-75, and 78.

Claims 1, 10, 20, 32, 56, 63, 75, and 78 are independent. The remaining claims depend, directly or indirectly, from one of the independent claims. Thus, remarks that refer to one or more independent claims apply equally to any claim that depends from a referenced independent claim. In the event that the present rejections may be applied to one or more of new claims 79-88, Applicants respectfully further traverse the application of the present rejections to new claims 79-88.

The subject matter of each independent claim and the teachings of Sirhan *et al.*, Hossainy *et al.*, and Whitbourne *et al.* are described above in connection with the rejections under 35 U.S.C. §102 and will not be reiterated in this section.

Once again, while the specific disclosures of Sirhan *et al.*, Hossainy *et al.*, and Whitbourne *et al.* (collectively, "the cited documents") differ somewhat, the relevant disclosure for analysis of the rejections is the same: each reference identifies a vast number of individual polymer species. Consequently, unless otherwise specifically indicated, the remarks that follow apply to each rejection.

Applicants submit that while the cited documents describe general types and classes of polymers from which polymers used to form the miscible polymer blends in Applicants' claims may be selected, the cited documents neither teach nor suggest the selection of the recited combinations of polymers. The cited documents provide no blaze marks that would

direct one skilled in the art to select polymers based on their miscibility and/or the recited differences in solubility parameter.

The Examiner suggests that Applicants' claims are obvious in view of the cited documents because each document describes classes of polymers that "[encompass] many of the same polymers and active agents as applicants [sic] currently claimed invention" (Examiner's Answer, page 10 with respect to Sirhan *et al.*, page 11 with respect to Hossainy *et al.*, and page 12 with respect to Whitbourne *et al.*) without considering that Applicants' claims are, in fact, directed to a subset of the possible combinations encompassed by the broad disclosures of general classes of polymers in the cited documents. The subset of polymer combinations to which Applicants' claims are drawn is small and specific in relation to all of the possible polymer combinations encompassed by the disclosures of the cited documents and is undisclosed in the cited documents. Moreover, the cited documents provide no teaching or suggestion that would direct one skilled in the art to Applicants' claimed subset of polymer combinations from among the innumerable generic polymer combinations described in the cited documents.

Applicants' position is supported by the decision of the Federal Circuit in *In re Baird*, 29 USPQ2d 1550 (1994). In that case, the appealed claim was directed to a flash fusible toner composition comprising a polyester of bisphenol A and an aliphatic carboxylic acid. *Id.* at 1551. The claim was rejected over a prior art reference that described developer compositions comprising a polymeric compound of a generic formula that encompassed the composition of the appealed claim. *Id.* The Board upheld the rejection using reasoning similar to that used to reject Applicants' present claims, "the fact that [the claimed] binder resin is clearly encompassed by the generic disclosure of [the prior art]...provides ample motivation for the selection of [the claimed composition]." *Id.*

The Federal Circuit reversed the Board's decision:

While the [prior art] formula unquestionably encompasses bisphenol A when specific variables are chosen, there is nothing in the disclosure of [the prior art] suggesting that one should select such variables. *Id.* at 1552. (emphasis added).

This reasoning by the Federal Circuit directly applies to the present case. Each of the cited documents encompasses at least some of Applicants' miscible polymer blends when specific variables—e.g., miscibility and/or differences in solubility parameters—are chosen. However, there is nothing in any of the cited documents, either alone or in combination with one another, suggesting that one should select those variables. As a result, the mere generic description of polymer combinations that encompass the claimed miscible polymer blends cannot render Applicants' claims unpatentable in the absence of some suggestion that the specific polymer combinations recited in Applicants' claims should be selected.

After *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), the rationale used by the Federal Circuit in *In re Baird* was reiterated in *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories Inc.*, 86 USPQ2d 1196 (Fed. Cir. 2008). The Federal Circuit reiterated that a claim cannot be rendered obvious by a prior disclosure that includes several unpredictable alternatives without some guidance to select features recited in the claim. The Federal Circuit contrasted a situation as presented in *KSR* (e.g., "a situation with a finite, and in the context of the art, small or easily traversed, number of options" 86 USPQ2d at 1201) with situations in which the path to the claimed subject matter is less direct. The Federal Circuit rejected the argument, based on language from *KSR*, that claims to a new drug were obvious in light of "a finite number of identified, predictable solutions" *Id.* The Federal Circuit noted that one skilled in the art, even if provided with a general class of compound from which to start, would not necessarily have chosen the starting compound selected by the patentee. *Id.*

In the present application, the cited documents describe innumerable polymer species, but provide no guidance to select polymers in relation to one another and based on the criteria recited in Applicants' claims. Consequently, the obviousness analysis with respect to Applicants' claims is similar to the analysis by the Federal Circuit in both *In re Baird* and *Ortho-McNeil*—both cases in which the claimed subject matter was found to be nonobvious—and distinguishable from the situation in *KSR*.

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For: ACTIVE AGENT DELIVERY SYSTEMS, MEDICAL DEVICES, AND METHODS

Applicants respectfully submit that claims 1-18, 20-75, and 78-88 comply with the requirements of 35 U.S.C. §103(a) and request that the rejections of claims 1-18, 20-75, and 78 as being unpatentable over Sirhan *et al.*, as being unpatentable over Hossainy *et al.*, and as being unpatentable over Whitbourne *et al.* be withdrawn.

Summary

It is respectfully submitted that the pending claims 1-18, 20-75, and 78-88 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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June 20, 2008

Date

CERTIFICATE UNDER 37 CFR §1.8:

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